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Integrated blood treatment module

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The present invention relates to an integrated extracorporeal blood treatment circuit, in particular for extracorporeal blood treatments using a filter.

Filters are used in various extracorporeal treatments of blood, such as hemodialysis, hemofiltration, hemodiafiltration, plasmapheresis. The same type of filter, usually referred to as hemodialyzer or hemofilter, is used for hemodialysis, hemofiltration, hemodiafiltration. The main difference between a hemodialyzer and a plasmafilter (i.e. a filter used in plasmapheresis) is the pore size of their respective membrane, a membrane for plasmapheresis allowing the proteins contained in blood to migrate therethrough, whereas a membrane for hemodialysis does not.

A conventional filter for extracorporeal treatment of blood comprises a first and a second compartments separated by a membrane, the first compartment having an inlet and an outlet for the circulation of blood therethrough and the second compartment having an outlet for draining a liquid (e.g. plasma water, plasma, used dialysis liquid) and an inlet when the treatment (e.g. hemodialysis) requires the circulation of a treatment liquid (e.g. a dialysis liquid) in the second compartment. The membrane is enclosed in an elongated tubular housing closed at both ends by an end-cap having a nozzle used as an inlet/outlet port for the first compartment.

In the above treatments, blood is withdrawn from the patient, flown through the first compartment of the filter, and returned to the patient. In hemodialysis, a dialysis liquid is simultaneously flown though the second compartment of the filter and the metabolic wastes (urea, creatinine) contained in blood migrate by diffusion through the membrane into the second compartment. In hemofiltration, a pressure difference is created across the membrane so that plasma water flows through the membrane into the second compartment of the filter. Here, metabolic wastes migrate by convection into the second compartment. In order to compensate for the loss of bodily fluid, the patient is simultaneously infused a sterile substitution solution. Hemodiafiltration is a combination of hemodialysis and hemofiltration, and, in this treatment, a dialysis liquid is flown through the second compartment

and a substitution liquid is infused into the patient. In plasmapheresis, a pressure difference is created across the membrane so that plasma (i.e. plasma water and proteins) flows through the membrane into the second compartment of the filter. Once treated, the plasma is returned to the patient.

A machine for performing any of the above treatments comprises a peristaltic pump for withdrawing blood from a patient through a so-called arterial line connected at one end to the vascular circuit of the patient and at the other end to the inlet of the first compartment of a filter, for pumping blood into the filter, and for returning blood to the patient through a so-called venous line connected at one end to the outlet of the first compartment of the filter and at the other end to the vascular circuit of the patient. The treatment machine also usually comprises a first blood pressure sensor for measuring the pressure of blood in the arterial line upstream of the pump, a second blood pressure sensor for measuring the pressure of blood in the arterial line downstream of the pump, a third pressure sensor for measuring the pressure of blood in the venous line, a bubble detector for detecting air bubbles in the venous line and a clamp for closing the venous line, for example when air bubbles are detected by the bubble detector.

An arterial line typically comprises the following components connected together by segments of flexible tubes: a first Luer connector for connection to an arterial cannula, an arterial bubble trap, a pump hose for cooperating with the rotor of the peristaltic pump of the treatment machine, and a second Luer connector for connection to the inlet of the first compartment of the filter.

A venous line typically comprises the following components connected together by segments of flexible tubes: a first Luer connector for connection to the outlet of the first compartment of the filter, a venous bubble trap, and a second Luer connector for connection to a venous cannula. Usually, the first and third pressure sensors of the machine are connected to the arterial and venous bubble trap respectively, when the treatment machine, the arterial line, the venous line and the filter are assembled in view of a treatment.

A conventional bubble trap is basically an elongated container that, in use, is held vertically. The container has an inlet and an outlet for blood that are arranged so as not to be adjacent. It comprises also, in an upper location, a pressure measuring port for connection to a pressure sensor, an infusion port for infusing a liquid (e.g. a drug or a sterile saline solution) and an injection port for adding or removing air into or from the bubble trap so as to adjust the level of blood therein. In use, the bubble trap contains a volume of blood in a lower part that transiently stagnates therein so as to let gas bubbles and micro bubbles escape by gravity and join an upper part of the container full of air. In a conventional bubble trap, there is therefore always an interface blood-air. In order to properly operate, conventional bubble traps must contain a certain volume of blood (which conflicts with the long lasting effort of minimizing the extracorporeal volume of blood in blood treatments). Also their use is limited to relatively short treatment sessions because of the blood clotting resulting from the permanent blood-air interface. In this respect, they are adapted to chronic treatment (a treatment session for a chronic patient usually lasts about four hours), but they cannot be used for intensive care treatment (the treatment of an acute patient can last several days).

The assemblage of an extracorporeal blood circuit as described above (i.e. the connection of the arterial and venous lines to the filter), the mounting thereof on a blood treatment machine, and the setting of the liquid level in the bubble traps is relatively time consuming.

An object of the invention is to design an integrated blood treatment module that can be mounted on a treatment machine faster than a conventional extracorporeal blood circuit and can be used for long lasting treatments.

According to the invention, an integrated blood treatment module comprises:

• a blood treatment device having:

- a housing having a longitudinal axis;

- a first end-cap closing a first end of the housing, the first end-cap having a blood inlet port;

- a second end-cap closing a second end of the housing;

- a filtration membrane arranged within the housing so as to delimit therein a first compartment and a second compartment;
- at least one access port for the second compartment connected to the housing;
• a pump hose for a peristaltic pump, wherein the pump hose has a first end that is secured to the filter and a second end that is connected to the blood inlet port so that the pump hose extends in a position that is complementary to the position of a race of the peristaltic pump; and
• an airless degassing device connected to the second end-cap having:
- a first chamber for receiving a liquid flowing out of the first compartment into the second end-cap,
- a second chamber in communication with the first chamber and having an opening closed by a hydrophobic membrane, and
- an outlet port connected to the second chamber for discharging the liquid.

Additional features are as follows:

- The integrated blood treatment module further comprises a first pressure measurement chamber that is secured to the blood treatment device and connected to the first end of the pump hose, the first pressure measurement chamber having a pressure measurement port for connection to a pressure sensor, the pressure measurement port having a central axis that is parallel to a central axis of the at least one access port of the second chamber.

- The integrated blood treatment module further comprises a second pressure measurement chamber that is secured to the blood treatment device and is connected to the outlet port of the blood degassing device, the second pressure measurement chamber having a pressure measurement port for connection to a pressure sensor, the pressure measurement port having a central axis that is parallel to a central axis of the at least one access port to the second chamber.

- The integrated blood treatment module further comprises a support structure having a plurality of conduits defined therein, the blood treatment device being secured to the support structure.

The integrated blood treatment module according to the invention presents several advantages. First, it is compact and allows for a significant reduction of the extracorporeal blood volume that is needed in extracorporeal blood treatments. Second, it does not require any specific activity for its mounting on a treatment machine nor for its setting in use (in particular, no adjustment of the level of the air-blood interface is needed in the degassing device). Third, since the degassing device operates without air-blood interface, the integrated blood circuit is particularly adapted to long lasting treatments (e.g. continuous renal replacement therapies).

Other additional or alternative features of the invention are as follows:

- The support structure comprises a first conduit having a first end connected to a first access port of the second compartment, and a second end in the form of an outlet nozzle having a central axis for connection to a drain tube.

- The support structure comprises a second conduit having a first end connected to a second access port of the second compartment and a second end in the form of an inlet nozzle having a central axis for connection to a dialysis liquid supply tube.

- The support structure comprises:

• a third conduit having an inlet for connection to a blood withdrawal line, and an outlet connected to the first end of the pump hose; and

• a fourth conduit having an inlet connected to the second end of the pump hose, and an outlet connected to the blood inlet port of the blood treatment device.

- The support structure comprises a fifth conduit having an inlet connected to the outlet port of the blood degassing device, and an outlet for connection to a blood return line.

- The second chamber of the blood degassing device is in communication with the first chamber through a passageway that has a lesser cross-section than a cross-section of the second chamber so that a flow of liquid from the first chamber into the second chamber decreases within the second chamber.

- The first chamber, the second chamber and the passageway therebetween are arranged with respect to each other so that a flow pattern of a liquid flowing from the first chamber, through the second chamber and to the outlet port comprises a component that is tangential to the hydrophobic membrane.

- The first chamber, the second chamber and the passageway therebetween are arranged with respect to each other so that a flow of liquid flowing from the first chamber, through the second chamber and to the outlet port keeps gas bubbles in motion along an inner surface of the hydrophobic membrane.

The blood degassing device that is part of the integrated blood treatment module according to the invention is very efficient and remains efficient over time. Also its allows for a compact design, i.e. a small internal volume. For example, It is possible to design such degassing device with a total internal volume that is about half of the blood volume in conventional bubble traps.

Other features and advantages of the invention will appear on reading the detailed description that follows. Reference will be made to the appended drawings in which:

Figure 1 is a perspective view of a first embodiment of the integrated blood treatment module according to the invention;

Figure 2 is a cross-section view of the upper end-cap assembly of the integrated blood treatment module of figure 1, along a plane that contains the central axis of the end-cap;

Figure 3 is a front view of a variant of the integrated blood treatment module of Figure 1;

Figure 4 is a perspective view of a second embodiment of the integrated blood treatment module according to the invention;

Figure 5 is a rear view of a of the integrated blood treatment module of figure 4;

Figure 6 is a perspective view, partially cut-away, of the upper portion of the integrated blood treatment module of figure 4;

Figure 7 is a cross-section view of the upper portion of the integrated blood treatment module of figure 4, along a plane that contains the longitudinal axis of the treatment device;

Figure 8 is a perspective view of a third embodiment of the integrated blood treatment module according to the invention;

Figure 9 is a rear view of a of the integrated blood treatment module of figure 8;

Figure 10 is a perspective view of a fourth embodiment of the integrated blood treatment module according to the invention;

Figure 11 is a rear view of a of the integrated blood treatment module of figure 10.

Figure 1 shows an integrated blood treatment module comprising a blood treatment device in the form of a hollow fiber filter 1 having a tubular housing 2 closed at one end by a lower end-cap assembly 4 and at the other end by an upper end-cap assembly 5 (in use, the integrated blood treatment module is held in a substantially vertical position, and the end-cap assemblies are referred to here by the respective position they occupy along a vertical line when the integrated blood treatment module is in use). The tubular housing 2, which has a longitudinal axis 3, contains a semi-permeable membrane in the form of a bundle of hollow fibers extending within the housing 2 and secured thereto at both ends by a potting compound in which they are embedded. The potting compound forms a disk that extends perpendicularly to the longitudinal axis 3 of the housing 2. The ends of the fibers open on an outer surface of the disks of potting material.

By construction, the hollow fiber filter 1 comprises a first and a second compartments separated from each other. The first compartment includes the

interior of the hollow fibers and the space delimited at each end of the filter between the outer surface of the disk of potting compound and the inner surface of the end-cap assemblies 4, 5, and the second compartment includes the space outside of the hollow fibers that is delimited by the inner surface of the housing and the inner surface of the disks of potting material. The housing 2 is fitted at both ends with nozzles 6, 7 that give access to the second compartment. The central axis of the nozzles 6, 7 are perpendicular to the longitudinal axis 3 of the housing 2.

A first and a second disk-shaped blood pressure measuring chambers 8, 9 are secured to the housing 2 at the vicinity of the two nozzles 6, 7, respectively. Each blood pressure measuring chamber 8, 9 comprises a blood compartment and an air compartment separated by a circular flexible membrane. The blood compartment comprises an inlet port 10 and an outlet port 11. The air compartment comprises a measurement port 12 for connection to a pressure sensor. The blood pressure measuring chambers 8, 9 are secured to the housing 2 so that the measurement ports 12 and the nozzles 6, 7 open in the same direction. The central axis of the nozzles 6, 7 and the central axis of the measurement ports 12 are substantially parallel and they are substantially perpendicular to the longitudinal axis 3 of the housing 2.

The lower end-cap assembly 4 comprises a circular end-wall 13 connected to a tubular peripheral wall 14 by which the end-cap 4 is secured to the housing 2. The end-wall 13 is substantially perpendicular to the longitudinal axis 3 of the filter 1 and the tubular peripheral wall 14 is concentric to the housing 2. The end-cap assembly 4 also comprises a L shaped inlet nozzle 15 having a longer branch connected to the end-wall 13 so that the central axis of this branch coincides with the longitudinal axis 3 of the housing 2, and a shorter branch that is connected to the downstream end 16 of a pump hose 17. Note the two triangular buttresses that are connected to diametrically opposed sides of the nozzle 15 and to the end-wall 13 in order to rigidify the nozzle 15. The upstream end 18 of the pump hose 17 is connected to a tubular connector 19 secured to the housing 2 so that the pump hose 17 forms a U shaped loop ready to cooperate with the rotor of a peristaltic pump (not shown). The U shaped loop lies within a plane slightly tilted with respect

to the longitudinal axis 3 of the filter 1. A first infusion port 21, in which the tip of a syringe is engaged, is connected by a piece of flexible tube to the inlet nozzle 15. A second infusion port 22 is connected by a piece of flexible tube to the connector 19. A blood withdrawal line (or arterial line) comprises a first segment 23 connected to the inlet 10 of the first pressure measuring chamber 8 and a second segment 24 connecting the outlet 11 of the first pressure measuring chamber 8 to the tubular connector 19, that is to the pump hose 17.

The upper end-cap assembly 5 comprises an annular end-wall 25 connected to a tubular peripheral wall 26 by which the end-cap 5 is secured to the housing 2. The end-wall 25 is substantially perpendicular to the longitudinal axis 3 of the filter 1 and the tubular peripheral wall 26 is concentric to the housing 2. The upper end-cap assembly 5 also comprises an airless blood degassing device 30 that is connected to the annular end-wall 25. The blood degassing device 30, which is shown in details in Figure 2, comprises an outlet port 35 that is connected by a first segment 27 of a blood return line (or venous line) to the inlet 10 of the second pressure measurement chamber 9. The blood return line comprises a second segment 28 that is connected to the outlet 11 of the second pressure measurement chamber 9. A third infusion port 29 is connected by a piece of flexible tube to the degassing device 30.

As shown in figure 2, the degassing device 30 comprises a first chamber 31 for receiving a liquid flowing out of the first compartment of the filter 1 into the end-cap assembly 5; a second chamber 32 in communication with the first chamber 31 and having an opening 33 closed by a hydrophobic membrane 34; and the outlet port 35, which is connected to the second chamber 32, for discharging the liquid.

The first chamber 31 is delimited by a funnel like wall 36 that is connected by its base to the end-wall 25 of the end-cap assembly 5. The funnel like wall 36 has a central axis 37 that coincides with the longitudinal axis 3 of the housing 2. In the direction of the flow, the first chamber 31 has therefore an upstream portion having a decreasing cross-section and a downstream portion having a constant cross-section (unless otherwise specified, "cross-section" means here and hereunder the transversal cross-section with respect to the central axis 37; also, the "direction of

flow" means the direction of flow from the first compartment of the filter 2 to the outlet port 35 through the first and the second chambers 31, 32 of the degassing device 30).

The second chamber 32 has an upstream portion and a downstream portion that extend on each side of a plane containing the mouth of the funnel like wall 36, which forms the passageway 38 between the first and the second chambers 31, 32. The downstream portion is delimited by a cylindrical wall 39 that is concentric to the tubular portion of the funnel like wall 36, and by a bottom wall 40 that is beveled with respect the central axis 37. The main reason for designing a bottom wall 40 that is beveled with respect the central axis 37 rather than a bottom wall that would be perpendicular to the central axis 37 and would be connected to a cylindrical wall having the same length as the tubular portion of the funnel like wall 36, is to limit the inner volume of the degassing device 30. It results from the respective arrangement of the first chamber 31 and of the downstream portion of the second chamber 22 that the second chamber forms an overflow for a liquid flowing from the first chamber 31 into the second chamber 32. Note that the outlet port 35 is connected to the second chamber 32 as far as possible from the passageway 38 between the two chambers.

The upstream portion of the second chamber 32 is delimited by a lid 41 that fits on the mouth of the cylindrical wall 29 and closes the degassing device 30. The lid 41 comprises a first wall 42, which is frusto-conical, connected to a second wall 43, which is cylindrical. Note that the first wall 42 comprises in fact two frusto-conical portions, the outer portion having an angle that is slightly larger than the angle of the inner portion. The first, frusto-conical, wall 42 is connected to the second, cylindrical, wall 43 by its smaller section. The lid 41 is secured to the cylindrical wall 39 by the larger section of its frusto-conical wall 42. The upstream portion of the second chamber 32 has therefore a decreasing cross-section. The lid 41 further comprises an inner annular shoulder 44 that extends at the junction between the frusto-conical wall 42 and the cylindrical wall 43. The opening defined by the inner annular shoulder 44 forms the opening 33 of the second chamber 32 mentioned above. The annular shoulder 44 supports the hydrophobic membrane 34 at the periphery thereof. The membrane 34 is secured to the lid 41 by an O-ring

45 resting on the shoulder 44 and against which a stopper 46 is tightly engaged. The stopper 46, which snugly fits within the cylindrical wall 43 of the lid 41, comprises a large hole 47 in its center through which the air removed from the liquid in the degassing device 30 can escape. Note that the membrane 34 does not abut on the inner surface of the stopper 46. The membrane 34 can therefore deform to a certain extent. When the positive pressure in the filter exceeds however a determined value, the membrane 34 abuts on the stopper 46 and does not run the risk of rupturing.

Two inlet ports 48, 49 are connected to the first chamber 31. The inlet ports 48, 49, can be used for the infusion of various liquid (e.g. a substitution liquid or a drug, when the filter is a hemofilter).

The walls 36, 39 and 40 that delimit the first chamber 21 and the downstream portion of the second chamber 32, and the ports 35, 48 and 49 connected thereto, can be made by molding in one piece from a plastic material. A biologically inert material like polycarbonate is appropriate when the filter is for medical use. The lid 41 can also be made in one piece by molding, from the same material as the walls 36, 39, 40. The hydrophobic membrane 34 can be made of polytetrafluoroethylene.

The airless degassing device 30 is particularly adapted to remove gas from blood in an extracorporeal circuit of blood. The operation of the degassing device 30 in connection with, for example, a hemofilter, is as follows. Before a treatment session, the integrated blood treatment module is secured to a treatment machine (not shown) in a substantially vertical position, with the degassing chamber being in the upper position. The pump hose 17 is engaged between the rotor and the circular race of a peristaltic pump that is a part of the machine. A bag of sterile saline solution is connected to the arterial line 23 and the solution is pumped by the peristaltic pump into the arterial line 23, and through the first pressure measurement chamber 8, the first compartment of the hemofilter 1, the degassing device 30, the second pressure measurement chamber 9 and the venous line 28, so as to rinse the extracorporeal blood circuit, to fill it with sterile saline solution and to remove air therefrom (preparatory steps called "priming" of the

extracorporeal blood circuit). At the end of this process, there is no more air in the degassing device 30. Then, the arterial line 23 is connected to a blood vessel of a patient, blood is pumped into the extracorporeal circuit while the saline solution flowing out of the venous line 28 is collected in a waste bag. When blood reaches the end of the venous line 28, the venous line is in turn connected to the vessel of the patient and the treatment proper can start.

In the hemofilter 1, the blood flows within the hollow fibers, enters the end-cap assembly 5, flows through the first chamber 31, pours into the second chamber 32 and leaves the degassing chamber 30 via the outlet port 35. Since the cross-section of the second chamber 32 at the level of the passageway 38 is substantially larger than the cross-section of the passageway 38 itself, the blood flow substantially decreases when blood enters the second chamber 32. This helps the bubbles and micro-bubbles that may be present in blood to move upwards by gravity towards the hydrophobic membrane 34. Also, because blood is directed by the funnel like wall 36 towards the hydrophobic membrane 34 and from then towards the frusto-conical wall 42 of the lid 41, the overall flow pattern of blood is umbrella like with a component that is tangential to the hydrophobic membrane 34. The membrane is therefore permanently swept and the creation of a static layer of blood foam on the inner surface of the membrane 34 is prevented. Instead, the bubble and micro-bubbles are kept in a permanent motion at the vicinity of the membrane 34, through which they pass shortly after entering the second chamber 32.

A prototype of the degassing device 30 was built. The diameter of the passageway 38 was 19 mm, the diameter of the second chamber 32 at the level of the passageway 38 was 32 mm, and the diameter of the hydrophobic membrane 34 was 26 mm. The distance between the passageway 38 and the hydrophobic membrane 34 was 5mm. The membrane was made of polytetrafluoroethylene and had a thickness of 0,13 mm and a pore size of 0.2 μm. The inner volume of the degassing device was 20 cm3. Bovine blood was circulated at a flow rate of 500ml/mn. in a closed loop circuit including a hemofilter fitted with the prototype of degassing device 30. The pressure in the degassing device was 50 mmHg. After four hours, 5 ml of air was injected in the circuit upstream of the hemofilter. After

15 minutes, the air injected in the circuit had been totally removed by the degassing device 30.

Figure 3 shows a variant of the integrated blood treatment module of figure 1, connected to a treatment machine. Only the lower end-cap assembly 4 is shown. In this embodiment, the first pressure measurement chamber 8 is secured to the filter 1 so that the blood outlet 11 thereof extends radially with respect to the longitudinal axis 3 of the filter 1. This embodiment also comprises a third pressure measurement chamber 50 for measuring the pressure of blood downstream of a peristaltic pump and upstream of the filter 1. The blood compartment of the third pressure measurement chamber 50 is directly connected to the blood inlet nozzle 15 of the filter 1, which extends along the axis 3 of the filter 1. The third pressure measurement chamber 50 and second pressure measurement chamber 8 are arranged with respect to each other so that a pump hose 17 connected at one end to the blood outlet 11 of the first chamber 8 and at the other end to the blood inlet 10 of the third chamber 50 forms a U that is substantially comprised in a plane containing the longitudinal axis 3 of the filter 1. The U shaped pump hose 17 is shown in operational engagement with a rotary peristaltic pump, that is the loop portion of the hose is inserted in the channel defined between the rotor 51 and the semi-circular race 52 of the pump.

Figures 4 to 7 show a second embodiment of the integrated blood treatment module according to the invention. This integrated blood treatment module comprises a support structure 60 having a plurality of conduits defined therein, a filter 100 and a blood degassing device 30 that are secured to the structure 60.

The filter 100 has the same overall construction as the filter 1 described above, save for the identical end-caps 101 that are closing its housing 2 at both ends. Each end-cap 101 comprises a circular end-wall 102 connected to a tubular peripheral wall 103 by which the end-cap 101 is secured to the housing 2. The end-wall 102 is substantially perpendicular to the longitudinal axis 3 of the filter 100 and the tubular peripheral wall 103 is concentric to the housing 2. The end-cap assembly 101 also comprises an inlet nozzle 104 (or outlet nozzle 105) that is connected to the end-wall 102 so as to extends radially with respect to the

longitudinal axis 3 of the housing 2. The end-caps 101 are mounted on the housing 2 so that the inlet and outlet nozzles 6, 7, 104, 105 of the first and second compartments of the filter 100 extend parallel to each other on the same side of the filter 1, the inlet nozzle 104 of the first compartment being adjacent to the outlet nozzle 7 of the second compartment and the outlet nozzle 105 of the first compartment being adjacent to the inlet nozzle 6 of the second compartment.

The support structure 60 essentially comprises an elongated flat body 61 and a lower and an upper braces 62, 63 that extend at both ends of the body 61, from the same side thereof. The elongated body 61 has an overall rectangular shape. It is slightly longer and slightly narrower than the filter 100. The function of the braces 62, 63 is to mechanically and fluidly connect the filter 100 to the structure 60. Each brace 62/63 comprises an upper and a lower sockets having parallel axis that are designed to receive a pair of adjacent inlet/outlet nozzles (104/7 or 105/6) of the filter 100. The distance between the two braces 62, 63 corresponds to the distance between the two pairs of nozzles 104/7 and 105/6 of the filter 100 so that the nozzles can be engaged in the braces and the filter 100 secured to the structure 60.

The support structure 60 comprises a plurality of conduits defined therein as well as a first and a second pressure measurement chambers 8, 9.

A first conduit 64, extending through the lower brace 62 and the body 61, connects the upper socket of the lower brace 62 to an outlet nozzle 65 for a used liquid (e.g. blood ultrafiltrate, or used dialysis liquid or both) that is connected to the body 61 on the side thereof opposite the filter 100.

A second conduit 66, extending through the upper brace 63 and the body 61, connects the lower socket of the upper brace 63 to an inlet nozzle 67 for a fresh treatment liquid (e.g. a fresh dialysis liquid) that is connected to the body 61 on the side thereof opposite the filter 100.

A third conduit 68, extending through the body 61, has a first segment that connects a blood withdrawal line 69 to an inlet 10 of the blood chamber of a first

pressure measurement chamber 8 and a second segment that connects the outlet 11 of the blood chamber of the first pressure measurement chamber 8 to the first end of a pump hose 17. The air chamber of the first pressure measurement chamber 8 is delimited by a circular lid having a central port 12 for connection to a pressure sensor.

A fourth conduit 70, extending through the lower brace 62 and the body 61, connects the lower socket of the lower brace 62 to the second end of the pump hose 17. Note that the pump hose 17 is connected to the third and fourth conduits 68, 70 so as to form a U shaped loop ready to engage a peristaltic pump.

A fifth conduit 71, extending through the body 61, has a first segment that connects the outlet port 35 of the blood degassing device 30 to an inlet 10 of the blood chamber of a second pressure measurement chamber 9 and a second segment that connects the outlet 11 of the blood chamber of the second pressure measurement chamber 9 to a blood return line 72. The air chamber of the second pressure measurement chamber 9 is delimited by a circular lid having a central port 12 for connection to a pressure sensor. Note that the central axis of the inlet and outlet nozzles 65, 67 and the central axis of the measurement ports 12 of the pressure measurement chambers 8, 9 are parallel.

A sixth conduit 73, extending through the body 61, connects an infusion line 74 to the fourth conduit 70.

A seventh conduit 75, extending through the body 61, connects an infusion line 76 to the fifth conduit 71.

Except the inlet of the fifth conduit 71 and the inlet of the sixth conduit 73, which open at the upper and lower side of the body 61 respectively (when the integrated blood treatment module is in an operational position), the inlet/outlet of the third, fourth, seventh conduits 68, 70, 75 and the outlet of the fifth conduit 71 open on the same side of the body 61. Note also that the two pressure measurement chambers 8, 9 are embedded in the body 61 between the inlet and outlet nozzles 65, 67 for the second compartment of the filter 100. Also since the third conduit 68

is embedded in the body 61 at a distance of both ends of the body 61 (i.e. of the filter 100), the loop formed by the pump hose 17 extends laterally with respect of the filter 100. It results from these various dispositions that the integrated blood treatment module of the figures 4 and 5 is particularly compact.

The body 61 can be made in one piece by molding of a plastic material with the conduits defined therein. Only the membrane of the two pressure measurement chambers 8, 9 and the lid that delimit the air compartment thereof have to be manufactured as separate components and mounted later on the body 61.

The blood degassing device 30 is connected by a conduit 77 to the upper socket of the upper brace 63. As apparent in figures 6 and 7, the blood degassing device 60 is the same as device represented in figure 2, save for the upstream part of its first chamber 31, that is conical with an increasing cross-section in the direction of flow.

Figures 8 and 9 show a third embodiment of the integrated blood treatment module according to the invention. This integrated blood treatment module comprises a support structure 80 having a plurality of conduits defined therein, a filter 100 and a blood degassing device 30 that are secured to the structure 80.

This third embodiment essentially differs from the second embodiment by the shape of its support structure 80 and the location of the third conduit 68 and of the first pressure measurement chamber 8, which determines the position of the pump hose 17. The overall function of the blood treatment device and of its various components remains the same.

More specifically, the features that are specific to the blood treatment device of Figures 8 and 9 are as follows:

- The flat elongated body 81 is substantially longer than the filter 100 and its is secured to the filter so that a substantial portion thereof extends beyond the filter with respect to the lower end-cap 101 of the filter 100.
- The third conduit 68 and the first pressure measurement chamber 8 are located in the lowest part of the body 81, whereas the fourth conduit 70 is adjacent to the

lower end-cap of the filter. It results from this arrangement that the loop formed by the pump hose 17 extends laterally with respect to the longitudinal axis 3 of the filter, just below the filter 100.

- The inlet of the third conduit 68, which is connected to the blood withdrawal line 69 opens on the lowest side of the elongated body 81.

- An eighth conduit 82, extending through the body 81, connects an infusion line 83 to the third conduit 68, downstream of the first pressure measurement chamber 8.

- The inlet of the eighth conduit 82 opens on the side of the elongated body 81 opposite to the side thereof to which the pump hose 17 is connected.

- The inlet of the sixth conduit 73, which is connected to the infusion line 74, opens on the side of the elongated body 81 opposite to the side thereof to which the pump hose 17 is connected.

Figures 10 and 11 show a fourth embodiment of the integrated blood treatment module according to the invention. This integrated blood treatment module comprises a support structure 90 having a plurality of conduits defined therein, a filter 100 and a blood degassing device 30 that are secured to the structure 90.

This fourth embodiment essentially differs from the second embodiment by the shape of its support structure 90 and the location of the third conduit 68 and of the first pressure measurement chamber 8, which determines the position of the pump hose 17. The overall function of the blood treatment device and of its various components remains the same.

More specifically, the features that are specific to the blood treatment device of figures 10 and 11 are as follows:

- The flat elongated body comprises a first long branch 91 and a second short branch 92, which are parallel, connected by a third transversal branch 93, the longitudinal axis of which is slightly inclined with respect to the longitudinal axis of the first and second branches 91, 92. The longitudinal axis of the three branches 91, 92, 93 are in the same plane. The first branch 91 has approximately the same length as the filter 100 and is connected by its lower end to the transversal branch 93, at the middle thereof. The third transversal branch 93 is slightly longer than

the diameter of the loop of a U shaped pump hose for a peristaltic pump adapted to pumping blood. The second short branch 92 is connected by its upper end to the lower end of the third branch 93.

- The third conduit 68 extends in the second branch 92 and in the third branch 93, along the longitudinal axis of the second branch 92, so that its outlet opens in the lower end of the transversal branch 93, on the face of the body 91, 92, 93 opposite the filter 100.

- The fourth conduit 70 extends in the first branch 91 and in the third branch 93 so that its inlet opens in the upper end of the transversal branch 93, on the face of the body 91, 92, 93 opposite the filter 100.

- The pump hose 17, which has a first end connected to the outlet of the third conduit 68 and a second end connected to the inlet of the fourth conduit 70, forms a loop that extends in a plane that is perpendicular to the plane containing the longitudinal axis of the three branches 91, 92, 93 of the body of the structure 90. Note that when the blood treatment module is held in its operative position, i.e. vertical, the inlet end of the pump hose 17 is lower than its outlet end. The purpose of this disposition is to help degas the pump hose during the priming of the blood treatment module.

- The inlet of the third conduit 68, which is connected to the blood withdrawal line 69 opens on the lowest side of the elongated body 91, 92, 93.

- An eighth conduit 82, extending through the short branch 92 of the body, connects an infusion line 83 to the third conduit 68, downstream of the first pressure measurement chamber 8.

- The seventh conduit 75 is connected to the fifth conduit 71 upstream of the second pressure measurement chamber 9.

- The inlet of the eight conduit 83 opens on one lateral side of the elongated body 91, 92, 93, whereas the inlet of the seventh conduit 75 and the outlet of the fifth conduit 71 opens on the other lateral side of the elongated body 91, 92, 93.

Claims

1. Integrated blood treatment module comprising:

• a blood treatment device (1, 100) having:

- a housing (2) having a longitudinal axis (3);

- a first end-cap (4) closing a first end of the housing (2), the first end-cap having a blood inlet port (15, 104);

- a second end-cap closing (5) a second end of the housing (2);

- a filtration membrane arranged within the housing (2) so as to delimit therein a first compartment and a second compartment;

- at least one access port (6, 7) for the second compartment connected to the housing (2);

• a pump hose (17) for a peristaltic pump, wherein the pump hose (17) has a first end (18) that is secured to the filter and a second end (16) that is connected to the blood inlet port (15, 104) so that the pump hose (17) extends in a position that is complementary to the position of a race of the peristaltic pump; and

• an airless degassing device (30) connected to the second end-cap (5) having:

- a first chamber (31) for receiving a liquid flowing out of the first compartment into the second end-cap (5),

- a second chamber (32) in communication with the first chamber (31) and having an opening (33) closed by a hydrophobic membrane (34), and

- an outlet port (35) connected to the second chamber (32) for discharging the liquid.

2. Integrated blood treatment module according to claim 1, further comprising a support structure (60, 80, 90) having a plurality of conduits (64, 66, 68, 70, 71, 73, 75, 82) defined therein, the blood treatment device (1, 100) being secured to the support structure (60, 80, 90).

3. Integrated blood treatment module according to claim 2, wherein the support structure (60, 80, 90) comprises a first conduit (64) having a first end connected to a first access port (7) of the second compartment, and a second end in the form of an outlet nozzle (65) having a central axis (3) for connection to a drain tube.

4. Integrated blood treatment module according to one of the claims 2 and 3, wherein the blood treatment device (1, 100) comprises a second access port (6) for the second compartment connected to the housing (2), and the support structure (60, 80, 90) comprises a second conduit (66) having a first end connected to the second access port (6) of the second compartment and a second end in the form of an inlet nozzle (67) having a central axis for connection to a dialysis liquid supply tube.

5. Integrated blood treatment module according to one of the claims 2 to 4, wherein the support structure (60, 80, 90) comprises:

- a third conduit (68) having an inlet for connection to a blood withdrawal line (69), and an outlet connected to the first end (18) of the pump hose (17); and
- a fourth conduit (70) having an inlet connected to the second end (16) of the pump hose (17), and an outlet connected to the blood inlet port (15) of the blood treatment device (1, 100).

6. Integrated blood treatment module according to one of the claims 2 to 5, wherein the support structure (60, 80, 90) comprises a fifth conduit (71) having an inlet connected to the outlet port (35) of the blood degassing device (30), and an outlet for connection to a blood return line (72).

7. Integrated blood treatment module according to claim 5, wherein the support structure (60, 80, 90) comprises a sixth conduit (73) having a first end connected to the fourth conduit (70) and a second end for connection to an infusion line (74).

8. Integrated blood treatment module according to claim 6, wherein the support structure (60, 80, 90) comprises a seventh conduit (75) having a first end connected to the fifth conduit (71) and a second end for connection to an infusion line (76).

9. Integrated blood treatment module according to claim 5, further comprising a first pressure measurement chamber (8) defined within the support structure (60,

80, 90) and connected to the third conduit (68) for measuring a pressure upstream of the pump hose (17).

10. Integrated blood treatment module according to claim 6, further comprising a second pressure measurement chamber (9) defined within the support structure (60, 80, 90) and connected to the fifth conduit (71) for measuring a pressure downstream of the blood degassing device (30).

11. Integrated blood treatment module according to claims 3, 4, 9, 10 wherein the first pressure measurement chamber (8) has a port (12) having a central axis for connection to a pressure sensor, the second pressure measurement chamber (9) has a port (12) having a central axis for connection to a pressure sensor and the respective central axis of the inlet nozzle (67), of the outlet nozzle (65), and of the port (12) of the first pressure measuring chamber (8) and of the port (12) of the second measuring chamber (9) are substantially parallel.

12. Integrated blood treatment module according to claim 11, wherein the respective central axis of the inlet nozzle (67), of the outlet nozzle (65), of the port (12) of the first pressure measuring chamber (8) and of the port (12) of the second measuring chamber (9) are substantially perpendicular to the longitudinal axis (3) of the housing (2).

13. Integrated blood treatment module according to claim 5, wherein the outlet of the third conduit (68) and the inlet of the fourth conduit (70) are arranged with respect to each other so that the pump hose (17) forms a loop that extends in a plane substantially parallel to the longitudinal axis (3) of the housing (2).

14. Integrated blood treatment module according to claim 13, wherein the outlet of the third conduit (68) is located between the two end-caps (4, 5) and the loop formed by the pump hose (17) extends laterally with respect to the housing (2) of the blood treatment device.

15. Integrated blood treatment module according to claim 13, wherein the outlet of the third conduit (68) is located along the longitudinal axis (3) of the housing (2)

beyond the first end-cap (4), and the loop formed by the pump hose (17) is offset along the longitudinal axis (3) of the housing (2) with respect to the housing (2) of the blood treatment device.

16. Integrated blood treatment module according to claim 13, wherein the outlet of the third conduit (68) and the inlet of the fourth conduit (70) are arranged with respect to each other so that the pump hose (17) forms a loop (17) that extends in a plane inclined with respect to a plane perpendicular to the longitudinal axis (3) of the housing (2).

17. Integrated blood treatment module according to claim 1, further comprising a first pressure measurement chamber (8) that is secured to the blood treatment device (1, 100) and connected to the first end (18) of the pump hose (17), the first pressure measurement chamber (8) having a pressure measurement port (12) for connection to a pressure sensor, the pressure measurement port having a central axis that is parallel to a central axis of the at least one access port (6, 7) of the second chamber (32).

18. Integrated blood treatment module according to one of the claims 1 and 17, further comprising a second pressure measurement chamber (9) that is secured to the blood treatment device (1, 100) and is connected to the outlet port (35) of the blood degassing device (30), the second pressure measurement chamber (9) having a pressure measurement port (12) for connection to a pressure sensor, the pressure measurement port (12) having a central axis that is parallel to a central axis of the at least one access port (6, 7) to the second chamber (32).

19. Integrated blood treatment module according to one of the claims 1, 17 or 18, further comprising a third pressure measurement chamber (50) that is secured to the blood treatment device (1, 100) and is connected to the second end (16) of the pump hose (17), the third pressure measurement chamber (50) having a pressure measurement port for connection to a pressure sensor, the pressure measurement port having a central axis that is parallel to a central axis of the at least one access port (6, 7) to the second chamber (32).

20. Integrated blood treatment module according to one of claims 1 to 22, wherein the second chamber (32) of the blood degassing device (30) is in communication with the first chamber (31) through a passageway (38) that has a lesser cross-section than a cross-section of the second chamber (32) so that a flow of liquid from the first chamber (31) into the second chamber (32) decreases within the second chamber (32).

21. Integrated blood treatment module according to claim 20, wherein the first chamber (31), the second chamber (32) and the passageway (38) therebetween are arranged with respect to each other so that a flow pattern of a liquid flowing from the first chamber (31), through the second chamber (32) and to the outlet port (35) comprises a component that is tangential to the hydrophobic membrane (34).

22. Integrated blood treatment module according to claim 21, wherein the flow pattern of a liquid flowing from the first chamber (31), through the second chamber (32) and to the outlet port (35) comprises an umbrella like component.

23. Integrated blood treatment module according to one of the claims 20 to 22, wherein the first chamber (31), the second chamber (32) and the passageway (38) therebetween are arranged with respect to each other so that a flow of liquid flowing from the first chamber (31), through the second chamber (32) and to the outlet port (35) keeps gas bubbles in motion along an inner surface of the hydrophobic membrane (34).

24. Integrated blood treatment module according to one of the claims 20 to 23, wherein the first chamber (31) comprises a downstream portion having a cross-section that is substantially the same as the cross-section of the passageway (38) between the first and the second chamber (32).

25. Integrated blood treatment module according to one of the claims 20 to 24, wherein the second chamber (32) has a downstream portion that surrounds the passageway (38) and forms an overflow for a fluid flowing from the first chamber (31) into the second chamber (32).

26. Integrated blood treatment module according to one of the claims 20 to 25, wherein the second chamber (32) has an upstream portion having a decreasing cross-section, with a larger cross-section that is substantially level with the passageway (38) and a smaller cross-section that is substantially level with the hydrophobic membrane (34).

27. Integrated blood treatment module according to one of the claims 20 to 26, wherein the second chamber (32) has a downstream portion that extends at least in part around a downstream portion of the first chamber (31).

28. Integrated blood treatment module according to claim 27, wherein the outlet port (35) opens into the downstream portion of the second chamber (32) at a location remote from the passageway (38).

Abstract

Integrated blood treatment module comprises:

- a blood treatment device (1, 100) having:

- a housing (2) having a longitudinal axis (3);

- a first end-cap (4) closing a first end of the housing (2), the first end-cap having a blood inlet port (15, 104);

- a second end-cap closing (5) a second end of the housing (2);

- a filtration membrane arranged within the housing (2) so as to delimit therein a first compartment and a second compartment;

- at least one access port (6, 7) for the second compartment connected to the housing (2);

- a pump hose (17) for a peristaltic pump, wherein the pump hose (17) has a first end (18) that is secured to the filter and a second end (16) that is connected to the blood inlet port (15, 104) so that the pump hose (17) extends in a position that is complementary to the position of a race of the peristaltic pump; and

- an airless degassing device (30) connected to the second end-cap (5) having:

- a first chamber (31) for receiving a liquid flowing out of the first compartment into the second end-cap (5),

- a second chamber (32) in communication with the first chamber (31) and having an opening (33) closed by a hydrophobic membrane (34), and

- an outlet port (35) connected to the second chamber (32) for discharging the liquid.

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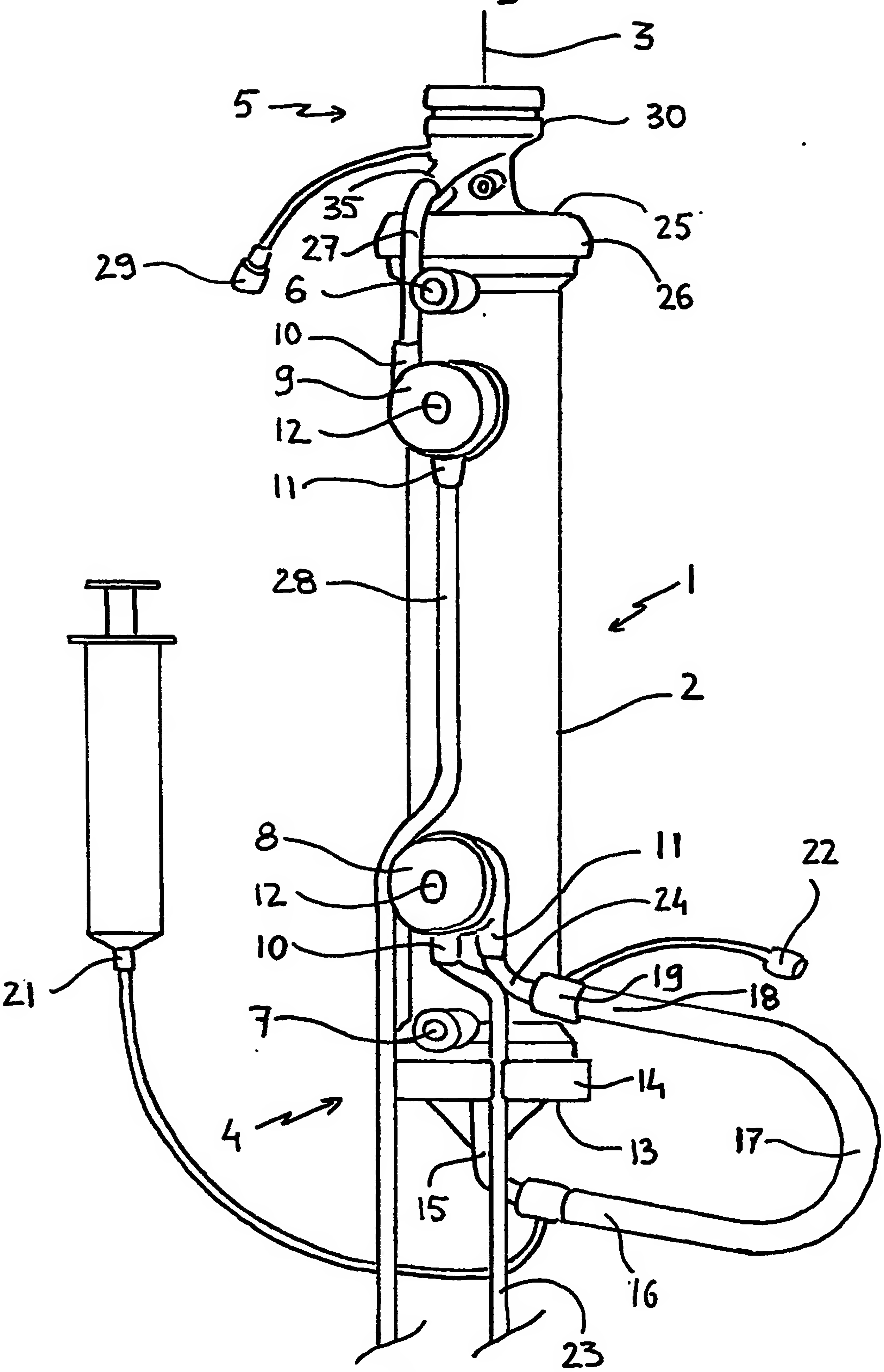

Fig. 1

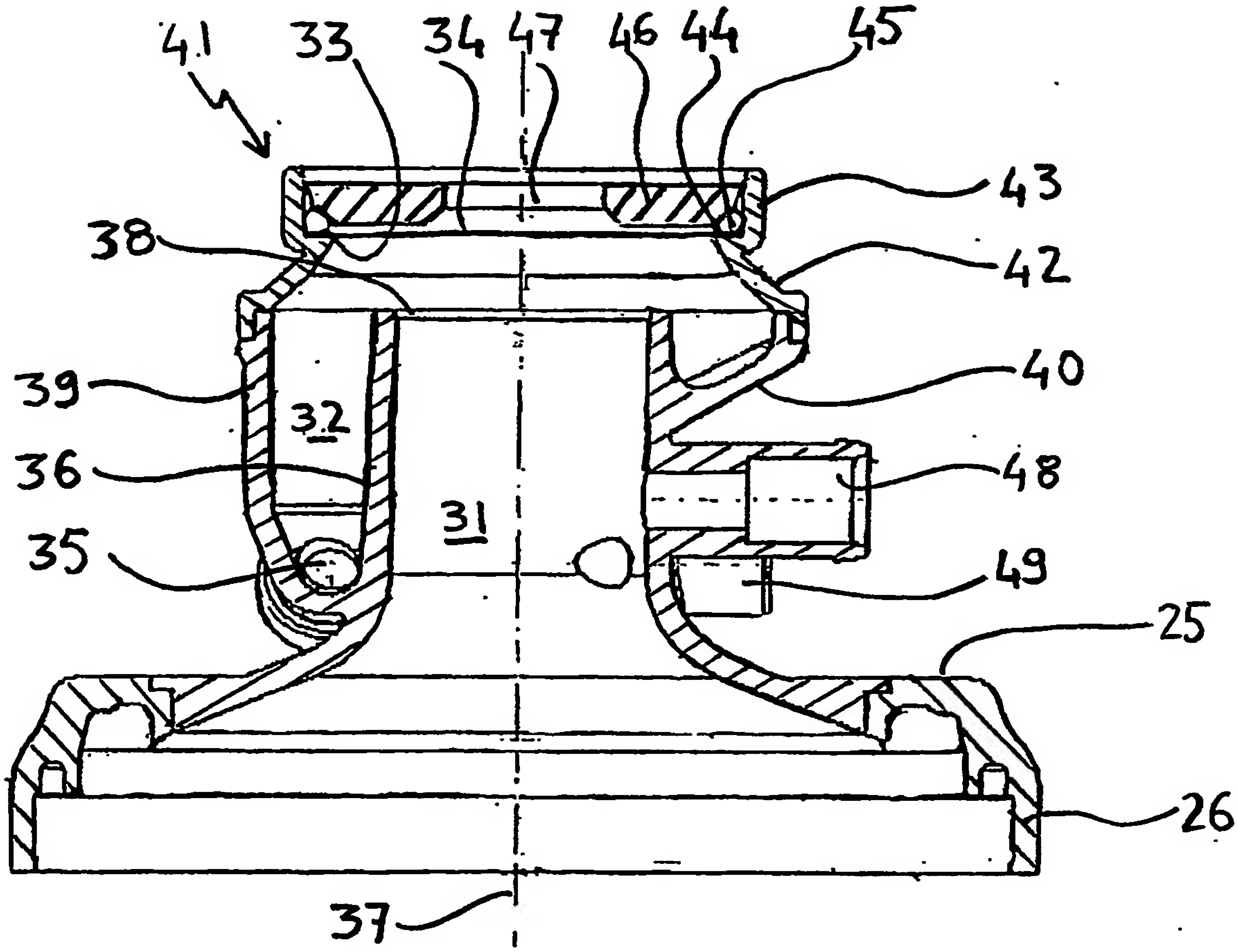
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Fig 2

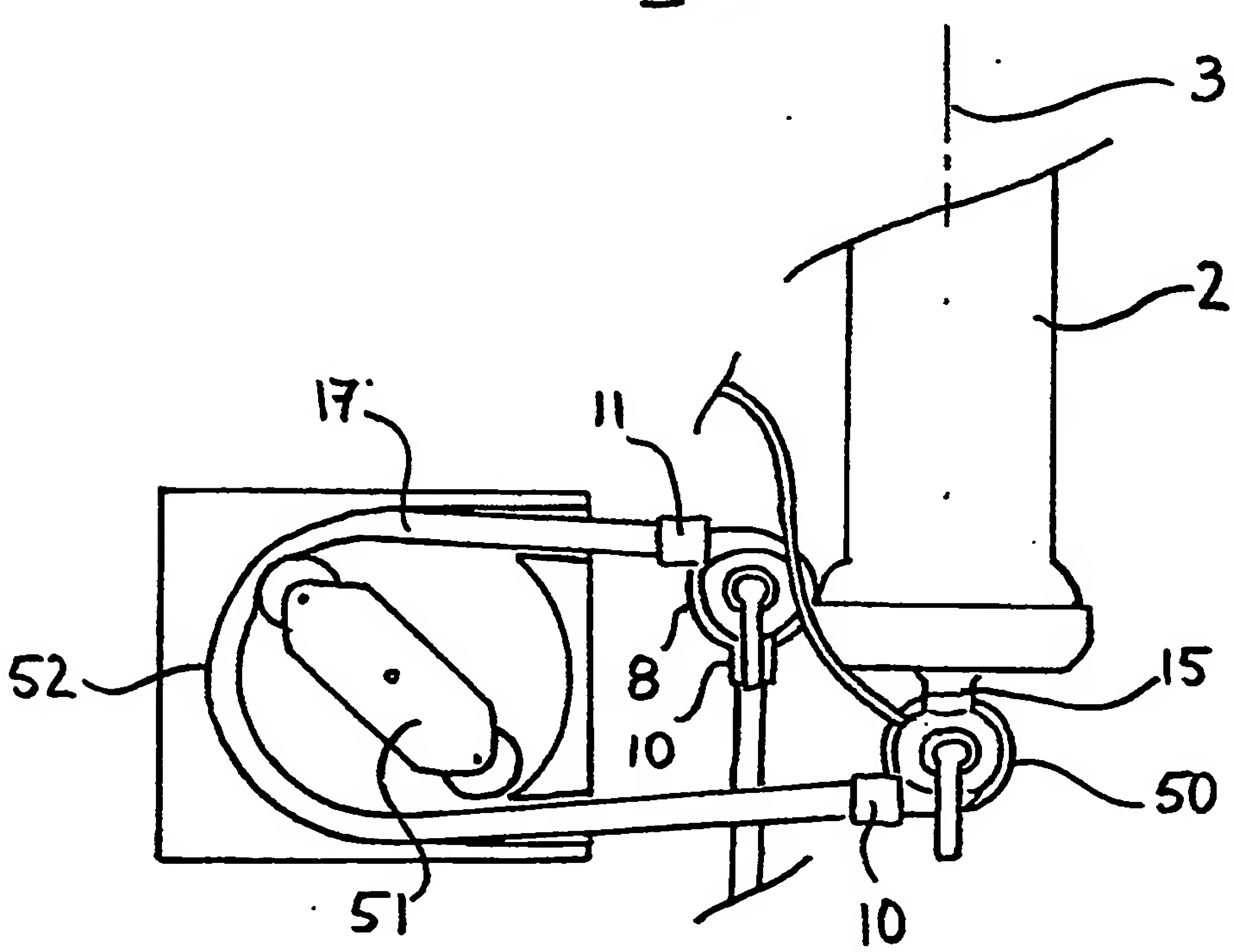
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Fig 3

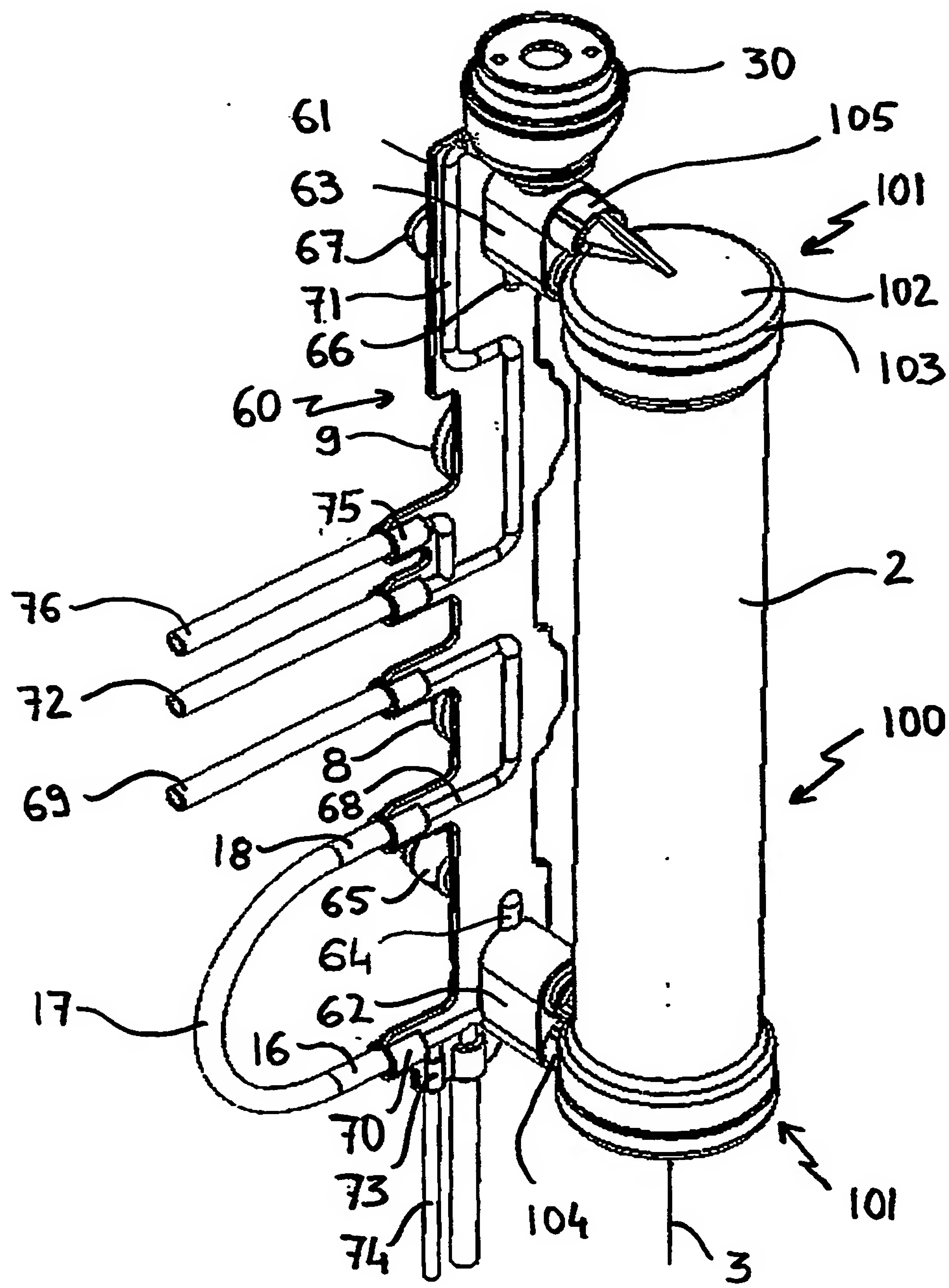
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Fig 4

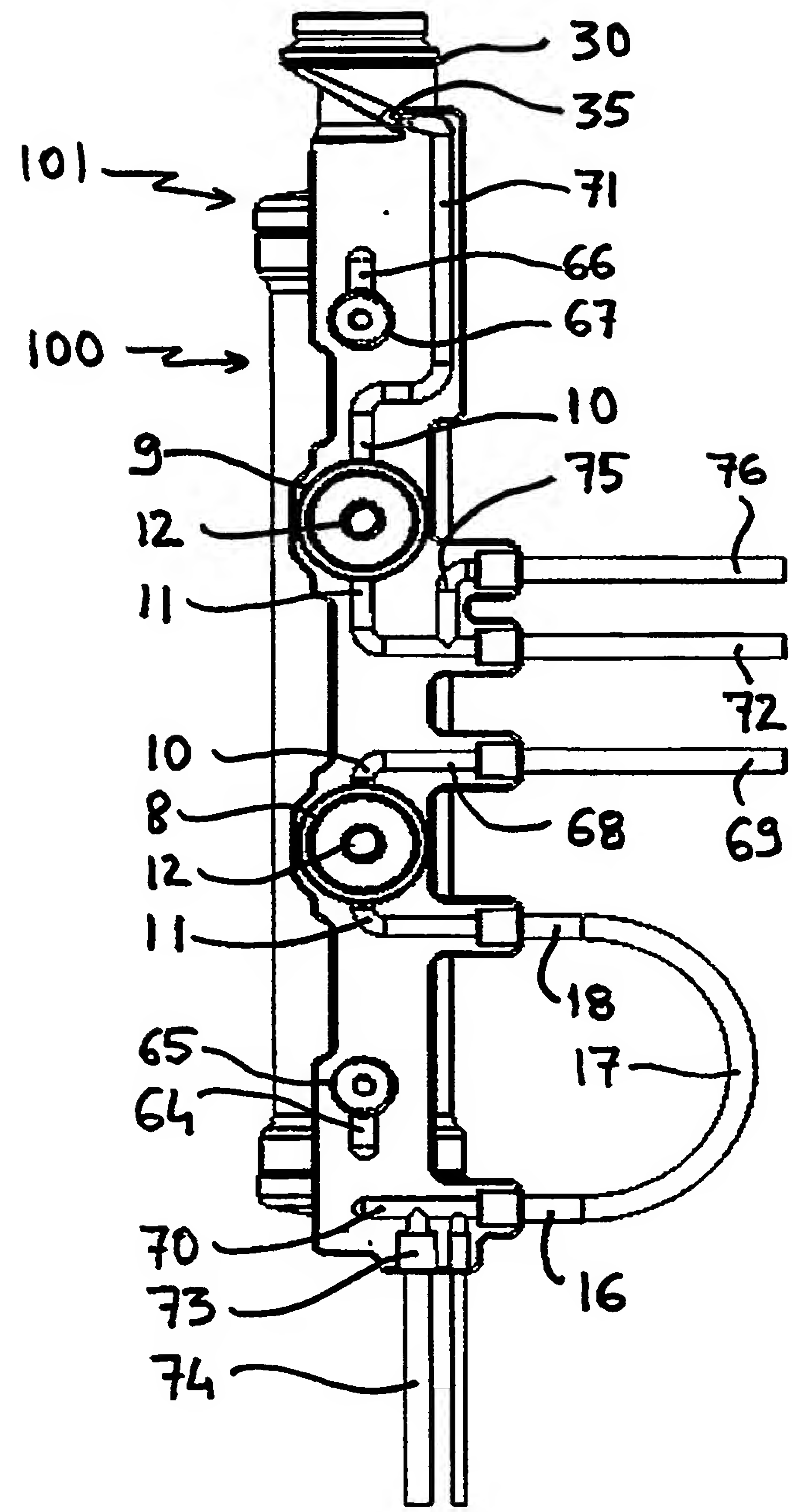
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Fig 5

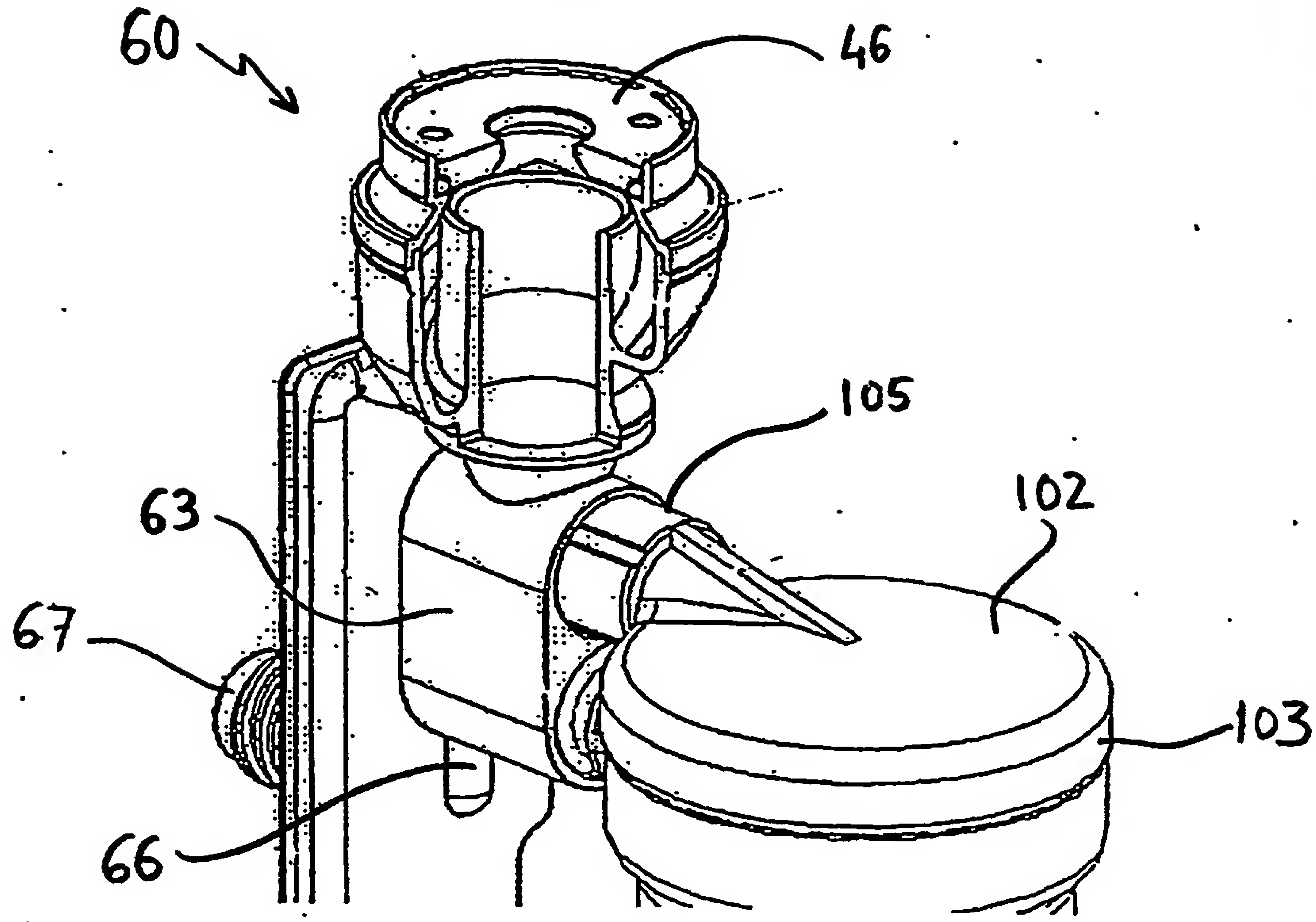

Fig 6

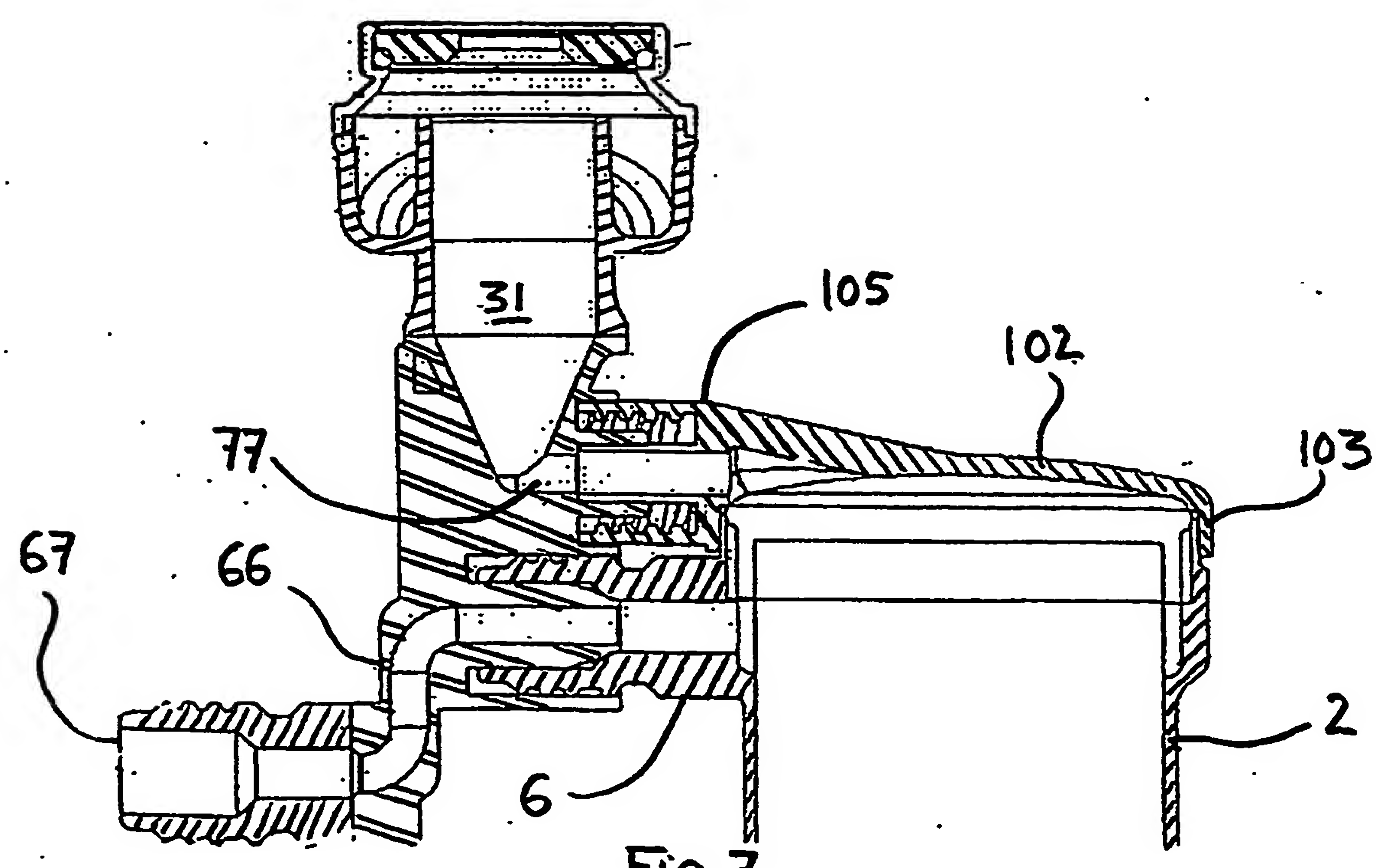

Fig.7

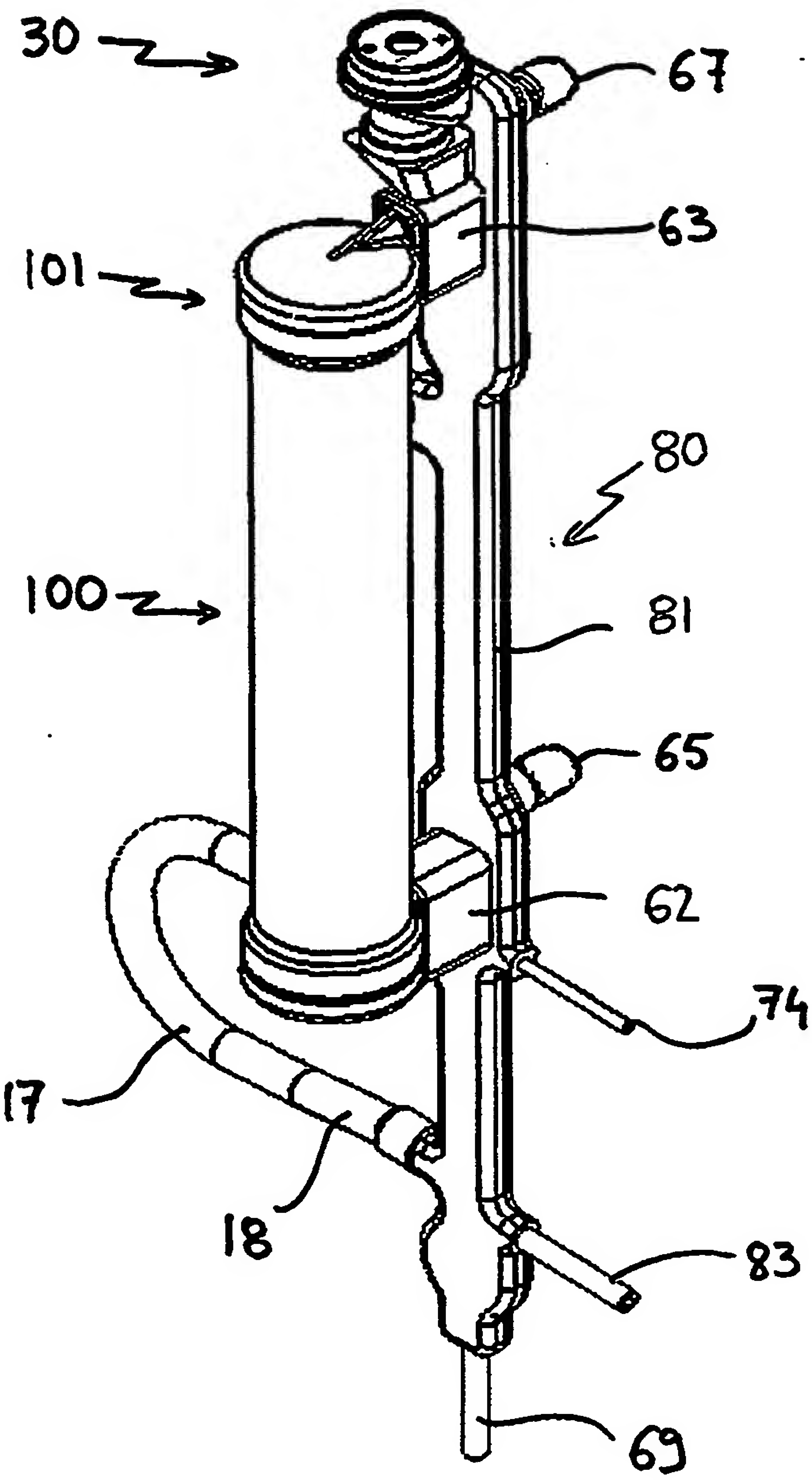

Fig. 8

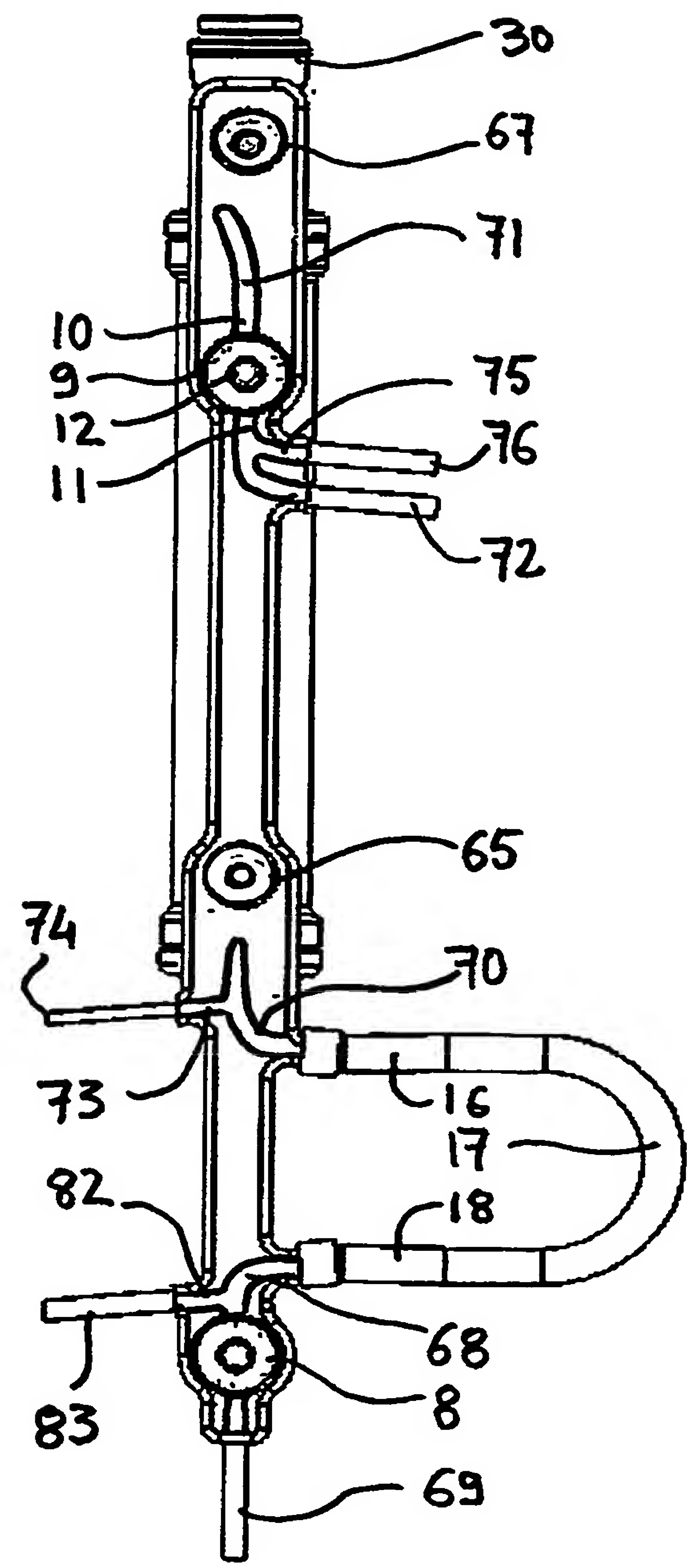

Fig. 9

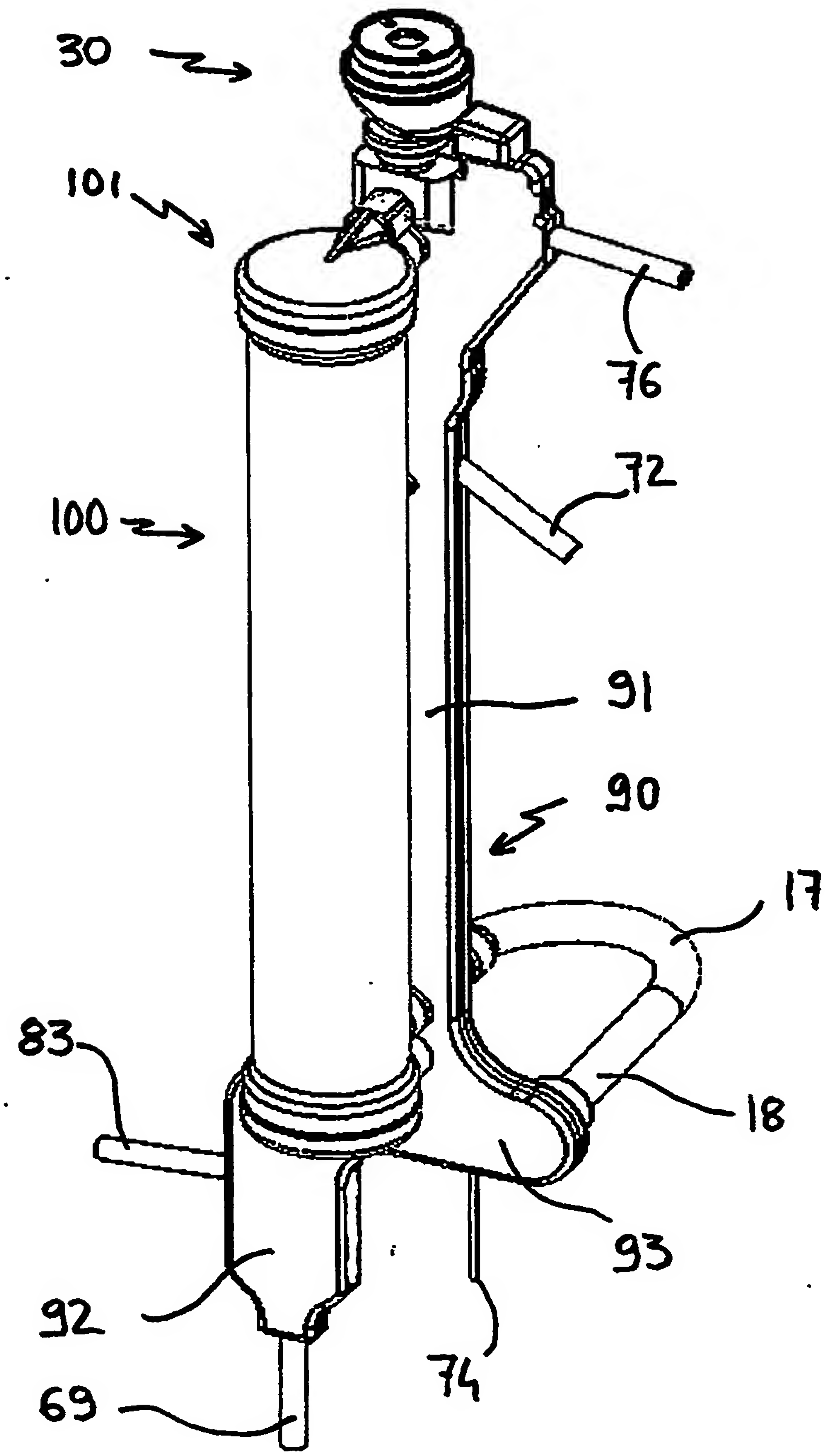

Fig. 10

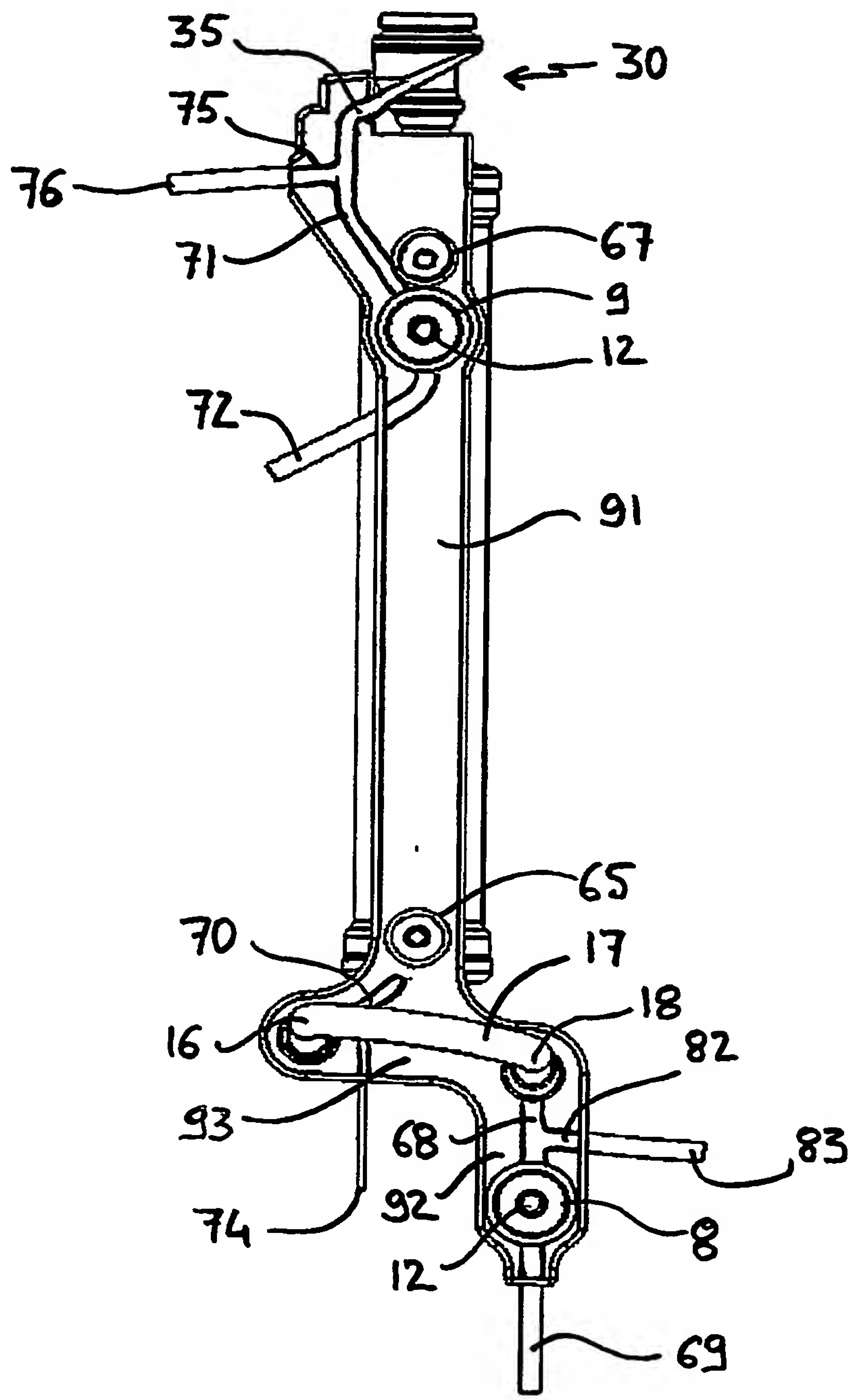

Fig. 11